IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE DEVELOPMENT INC., SHIRE PHARMACEUTICAL DEVELOPMENT, INC., COSMO TECHNOLOGIES LIMITED, and GIULIANI INTERNATIONAL LIMITED,	)	
Plaintiffs,	)	Civil Action No. 10-581 (KAJ)
v.	)	
CADILA HEALTHCARE LIMITED (d/b/a ZYDUS CADILA) and ZYDUS PHARMACEUTICALS (USA) INC.,	)	
Defendants.	)	

MEMORANDUM OPINION

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JORDAN, Circuit Judge, sitting by designation

I. INTRODUCTION

This opinion addresses issues of claim construction raised in the patent infringement action brought by Plaintiffs Shire Development LLC, Shire Pharmaceuticals Development Inc., Cosmo Technologies Limited, and Nogra Pharma Limited (collectively, "Shire") against Defendants Cadila Healthcare Limited d/b/a Zydus Cadila and Zydus Pharmaceuticals (USA) Inc. (collectively, "Zydus"). The suit is based on Zydus's submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA"), which, with Zydus's Paragraph IV certification under the Hatch-Waxman Act, constituted a technical act of infringement. 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (noting that § 271(e)(2) creates "a highly artificial act of infringement that consists of submitting an ANDA ... containing the fourth type of certification"). With its ANDA, Zydus seeks FDA approval to market a generic version of Shire's Lialda® product, a drug used to treat inflammatory bowel diseases. Shire contends that the pharmaceutical compositions described in Zydus's ANDA would, if marketed, infringe claims 1 and 3 of U.S. Patent No. 6,773,720 (the "'720 patent"), which Shire owns. The parties dispute the scope and meaning of a number of terms in the asserted claims of the '720 patent.

II. LEGAL STANDARDS

The general rules of claim construction are well-established, *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), and need not be repeated here.

III. RELATED CASES

In addition to filing suit against Zydus, Shire has also asserted the '720 patent against three other generic applicants: (1) *Shire Development LLC v. Osmotica Pharmaceutical Corp.*, 1:12-cv-00904 (N.D. Ga.) (filed Mar. 16, 2012); (2) *Shire Development LLC v. Watson Pharmaceuticals, Inc.*, No. 12-60862, 2013 WL 1912208 (S.D. Fla. May 9, 2013) (filed May 8, 2012); and (3) *Shire Development LLC v. Mylan Pharmaceuticals, Inc.*, 8:12-cv-01190 (M.D. Fla.) (filed May 25, 2012). In each of those cases, the district courts have issued claim construction orders construing many of the same terms in dispute here.

In *Shire Development LLC v. Watson*, the district court determined that claims 1 and 3 of the '720 patent were valid and infringed. 2013 WL 1912208 (S.D. Fla. May 9, 2013). On appeal, Watson challenged the constructions given for "inner lipophilic matrix" and "outer hydrophilic matrix" – two of the disputed claim terms that are currently before me. Applying *de novo* review, the Federal Circuit reversed the district court's construction of those terms and remanded for further proceedings.[1] *Shire Dev. LLC v. Watson Pharms., Inc.*, 746 F.3d 1326, 1331-34 (Fed. Cir. 2014) (*Watson I*).

Soon thereafter, in January 2015, the Supreme Court issued its opinion in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 840-41 (2015), holding that a district court's factual findings incident to claim construction must be reviewed for clear error. The Supreme Court vacated *Watson I* and remanded the case to the Federal Circuit for further consideration in light of *Teva*. *Shire Dev. LLC v. Watson Pharm., Inc.*, 135 S. Ct. 1174 (2015).

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[1] Because the Federal Circuit only reversed the district court's construction as to "inner lipophilic matrix" and "outer hydrophilic matrix," the district court's constructions of the other disputed terms are still relevant and given consideration here.

On June 3, 2015, the Federal Circuit issued its opinion on remand. In *Shire Development LLC v. Watson Pharmaceuticals, Inc.*, the Federal Circuit held that its decision in *Watson I* did not implicate factual findings to which deference was owed under *Teva*. 787 F.3d 1359, 1368 (Fed. Cir. 2015) (*Watson II*). Thus, the Federal Circuit incorporated its decision and reasoning from *Watson I* into *Watson II* and reaffirmed its reversal of the district court's construction of the terms "inner lipophilic matrix" and "outer hydrophilic matrix," as well as the reversal of the associated infringement finding. *Id.*

IV. THE '720 PATENT

The '720 patent concerns controlled-release oral pharmaceutical compositions for treating inflammatory bowel diseases, such as Crohn's disease and ulcerative colitis. ('720 patent at 1:9-13.) The active ingredient in the compositions is 5-amino-salicylic acid, also known as mesalamine. (*Id.* at 1:4-6.) The '720 patent has only one independent claim, claim 1, and three dependent claims, claims 2, 3, and 4. The parties dispute the construction of seven terms, all of which appear in claim 1 of the '720 patent.[2]

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[2] Claim 1 of the '720 patent reads as follows:

1. Controlled-release oral pharmaceutical compositions containing as an active ingredient 5-amino-salicylic acid, comprising:

a) an inner lipophilic matrix consisting of substances selected from the group consisting of unsaturated and/or hydrogenated fatty acid, salts, esters or amides thereof, fatty acid mono-, di- or triglycerids, waxes, ceramides, and cholesterol derivatives with melting points below 90° C., and wherein the active ingredient is dispersed both in said the lipophilic matrix and in the hydrophilic matrix;

b) an outer hydrophilic matrix wherein the lipophilic matrix is dispersed, and said outer hydrophilic matrix consists of compounds selected from the group consisting of polymers or copolymers of acrylic or methacrylic acid, alkylvinyl polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrins, pectins, starches and derivatives, alginic acid, and

A. "inner lipophilic matrix"

Shire contends that the term "inner lipophilic matrix" means "a macroscopically homogenous structure in all its volume that consists of at least one lipophilic excipient where the matrix itself exhibits lipophilic characteristics and is separate from the outer hydrophilic matrix." (D.I. 337 at 6-10.) Zydus responds that the term means "a matrix that exhibits lipophilic properties and cannot have hydrophilic properties, and controls the release of the active ingredient." (D.I. 344 at 8-11.) I conclude that the proper construction of "inner lipophilic matrix" is "a matrix that exhibits lipophilic properties and is separate from the outer hydrophilic matrix."

My construction of "inner lipophilic matrix" is based primarily on the Federal Circuit's recent decision in *Watson II*. In that case, the Federal Circuit reversed the district court, which had previously construed the term to mean "a matrix including at least one lipophilic excipient, where the matrix is located within one or more other substances." *Watson II*, 787 F.3d at 1365-68. The Federal Circuit determined that the district court's construction was "impermissibly broad" because it improperly focused on the properties of the excipients within the matrix, as opposed to the properties of the matrix itself. *Id.* at 1365. The Court concluded that "inner lipophilic matrix" and "outer hydrophilic matrix," as recited in claim 1, are necessarily separate

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natural or synthetic gums;

c) optionally other excipients;

wherein the active ingredient is present in an amount of 80 to 95% by weight of the total composition, and wherein the active ingredient is dispersed both in the lipophilic matrix and in the hydrophilic matrix.

('720 patent at claim 1.)

matrices that exhibit wholly different characteristics – the inner lipophilic matrix exhibits lipophilic properties while the outer hydrophilic matrix exhibits hydrophilic properties. *Id.* at 1367-68.

The Federal Circuit explained its conclusion in *Watson II* as being based on the claims of the '720 patent. First, it noted that the structure of claim 1 requires two separate matrices because the claim differentiates element (a), which recites an "inner lipophilic matrix," from element (b), which recites an "outer hydrophilic matrix." *Id.* at 1366. Second, the Court stated that a logical reading of claim 1 leads to the conclusion that the matrices are separated because the matrices are defined "by mutually exclusive spatial characteristics – one inner, one outer – and [by] mutually exclusive compositional characteristics – one hydrophilic, one lipophilic." *Id.* at 1366-67. Third, the Court reasoned that the matrices must be separate because the *Markush* groups[3] in claim 1 limiting the composition of the "inner lipophilic matrix" and "outer hydrophilic matrix" do not have overlapping components. *Id.* at 1367 (citing '720 patent at 6:11-14, 20-25).

The Federal Circuit also concluded that the specification of the '720 patent teaches "separate" matrices. *Id.* The Court noted that the specification "describes five examples of forming discrete lipophilic matrix granules and compressing those granules together with the hydrophilic matrix," and further states that a lipophilic matrix "opposes some resistance to the penetration of the solvent due to the poor affinity towards aqueous fluids." *Id.* (citing '720 patent at 3:31-45, 1:17-20.) Consequently, the Court reasoned that, because the parties have stipulated

[3] "A Markush group is a form of drafting a claim term ... to limit the claim to a list of specified alternatives." *Abbott Labs. v. Andrx Pharm., Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007).

that "lipophilic" means "poor affinity towards aqueous fluids," "the matrix that is deemed the 'lipophilic' matrix cannot have hydrophilic properties." *Id.* But, as the Federal Circuit noted, "a matrix comprised of only one lipophilic substance and several hydrophilic substances – and thus capable of exhibiting hydrophilic properties – would meet the district court's construction of 'lipophilic matrix.'" *Id.* That result, according to the Federal Circuit, was untenable because it "contradicts the customary and ordinary meaning of 'lipophilic' and 'hydrophilic.'" *Id.*

Accepting that reasoning, I find that the "inner lipophilic matrix" as described in the '720 patent must exhibit lipophilic properties. Despite Zydus's urging, however, I do not read the Federal Circuit's opinion in *Watson II* to require inclusion of the limitation that the "inner lipophilic matrix" "cannot have hydrophilic properties." Adding that limitation would be, as the *Mylan* court noted, redundant and potentially confusing. *See Mylan*, 2015 WL 1345322, at *5-*6. In *Mylan*, the district court construed "inner lipophilic matrix" to mean a matrix "that is separate from the outer hydrophilic matrix and that has poor affinity towards aqueous fluids." *Id.* at *6. The *Mylan* court reasoned that "a matrix that is lipophilic ... is necessarily one that is not hydrophilic. Therefore, defining a lipophilic matrix as one that is additionally not hydrophilic is circular and, rather than adding precision, adds only confusion." *Id.* at *5. I agree with the *Mylan* court's conclusion and thus decline to include the limitation that the "inner lipophilic matrix" "cannot have hydrophilic properties."[4]

With regards to Zydus's proposed inclusion of the phrase "controls the release of the active ingredient," I agree with Shire that such language imposes an unwarranted limitation.

[4] My construction is thus different from that in *Osmotica*, where the district court interpreted the Federal Circuit's decision in *Watson II* to require inclusion of the limitation that the "inner lipophilic matrix" "does not have an affinity for water." *Osmotica*, Doc. 173 at 17-18.

Zydus argues that both the specification, (*see e.g.*, '720 patent at col. 1 ll. 14–20, 32–33 (describing lipophilic matrix as sustaining, controlling, delaying, or otherwise modifying release by providing resistance to the penetration of solvent)), and the prosecution history, (*see, e.g.*, 720 Pros. Hist. at PLMESA03534253 (stating that "[t]he two matrices . . . provide for the control and extended dissolution of the active ingredient")), instruct that the "inner lipophilic matrix" controls the release of mesalamine. But, as noted by the Federal Circuit, limitations from a patent's specification are not to be read into the claims of the patent. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1326 (Fed. Cir. 2002). Indeed, simply because "claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957 (Fed. Cir. 1983). Because the claim itself does not require that the "inner lipophilic matrix" controls the release of the active ingredient, I decline to include such a limitation in the construction.

To repeat, then, I construe the term "inner lipophilic matrix" to mean "a matrix that exhibits lipophilic properties and is separate from the outer hydrophilic matrix."

B. "outer hydrophilic matrix"

Shire argues that "outer hydrophilic matrix" should be construed to mean "a macroscopically homogenous structure in all its volume that consists of at least one hydrophilic excipient where the matrix itself exhibits hydrophilic characteristics and is separate from the inner lipophilic matrix." (D.I. 337 at 10.) Zydus, on the other hand, contends that the proper construction of the term is "a matrix that exhibits hydrophilic characteristics and cannot have lipophilic properties, is separate from the inner lipophilic matrix, and controls the release of the active ingredient, in which the inner lipophilic matrix is dispersed." (D.I. 344 at 8.) I construe

the term "outer hydrophilic matrix" to mean "a matrix that exhibits hydrophilic properties[5] and is separate from the inner lipophilic matrix."

Because the terms are related, "outer hydrophilic matrix" must be construed in the same manner as "inner lipophilic matrix." Thus, the reasoning set forth above for the proper construction of "inner lipophilic matrix" applies here as well: based on the specification of the '720 patent and the Federal Circuit's decision in *Watson II*, the hydrophilic matrix must exhibit hydrophilic properties, but including the limitation that it "cannot exhibit lipophilic properties" is redundant and potentially confusing.[6] Also, the claim does not require that the outer hydrophilic matrix control the release of the active ingredient, so that limitation should not be imported from the specification. In short, I construe "outer hydrophilic matrix" to mean "a matrix that exhibits hydrophilic properties and is separate from the inner lipophilic matrix."

C. "melting points"

Shire contends that "melting points" should be construed to mean "the temperature at which a solid begins to change from solid to liquid." (D.I. 337 at 12.) Zydus argues that the term means "the temperature at which solid and liquid phases of a compound are at equilibrium." (D.I. 344 at 15.) I conclude that the proper construction of "melting points" is "the temperature at which solid and liquid phases of a compound are at equilibrium."[7]

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[5] Both Shire and Zydus use the term "characteristics" instead of "properties" to describe "hydrophilic" in their constructions. Because I perceive no difference between the terms, for consistency, I use the term "properties."

[6] My construction thus departs from that in *Osmotica*, where the district court interpreted the Federal Circuit's decision in *Watson II* to require inclusion of the limitation that the "outer hydrophilic matrix" "does not have lipophilic properties." *Osmotica*, Doc. 173 at 18.

[7] My construction differs from those in *Osmotica* and *Watson*, but in neither of those cased did the defendant propose the construction that Zydus proposes here. Instead, the dispute

The '720 patent does not define the term "melting point" and neither the patent nor the prosecution history provide insight into the term's meaning. Both Shire and Zydus argue that their constructions reflect the plain and ordinary meaning of the term and are supported by extrinsic evidence.

Shire relies on a number of dictionaries to support its construction. *See Merriam Webster's Collegiate Dictionary* 724 (10th ed. 1994) (defining "melt" as "to become altered from a solid to a liquid state by heat," and "melting point" as "the temperature at which a solid melts"); *McGraw-Hill Dictionary of Science and Technology Terms* 1236-37 (5th ed. 1994) (defining "melting point" as "the temperature at which a pure substance changes to a liquid"); *Chambers Science and Technology Dictionary* 562 (Peter M.B. Walker ed., 1988) ("The temperature at which a solid begins to liquefy."); *Larousse Dictionary of Science and Technology* 689 (1st ed. 1995) (same).

Zydus, conversely, relies on scientific textbooks and treatises in the field of physical pharmacy and chemistry to support its construction. *See* T.W. Graham Solomons, *Organic Chemistry* 76 (5th ed. 1992) ("The melting point of a substance is the temperature at which an equilibrium exists between the well-ordered crystalline state and the more random liquid state."); Alfred Martin, *Physical Pharmacy* 31 (4th ed. 1993) ("The ... melting point of a pure crystalline solid is strictly defined as the temperature at which the pure liquid and solid exist in

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in *Osmotica* centered around whether "melting points" referred to the temperature at which a solid "begins" to change to liquid. As in this case, Shire proposed insertion of the term "begins" in its construction, which the *Osmotica* court rejected. *Osmotica*, Doc. 173 at 12-13. The court construed the term to mean "the temperature at which each of the lipophilic substances (or excipients) which forms the lipophilic matrix changes from a solid to a liquid." *Id.* at 19. The district court in *Watson* construed the term to include the word "begins," but, in that case, the defendant agreed to its inclusion. *Watson*, 2013 WL 174843, at *9.

equilibrium."); Raymond Chang, *Chemistry* (4th ed. 1991) ("The temperature at which solid and liquid phases coexist in equilibrium.").

The Federal Circuit has said that "a general dictionary definition is secondary to the specific meaning of a technical term as it is used and understood in a particular technical field." *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1580 (Fed. Cir. 1996). Zydus's proposed construction is taken directly from textbooks and treatises in the relevant field of physical pharmacy and chemistry[8] and thus is the better construction of the disputed term. Moreover, Shire's expert, Dr. Pintal, stated in this deposition that, "[i]n order for the melting to take place, you have to be at the melting temperature, which is the temperature[] where [the solid and liquid phases] coexist in equilibrium." (D.I. 345 Ex. M at 46:10-13.) Thus, Dr. Pintal agreed that Shire and Zydus's constructions are "consistent descriptions of melting points" and refer to "the same phenomena." (*Id.* at 46:10-13, 57:8-11.)

Accordingly, I construe the term "melting points" to mean "the temperature at which solid and liquid phases of a compound are at equilibrium."

D. "dispersed"

Shire argues that the proper construction of "dispersed" is "sufficiently mixed to incorporate one substance into another," (D.I. 337 at 15), while Zydus contends that the term

[8] The parties appear to agree that a person having ordinary skill in the art would have at least a Bachelor's or Master's degree in an appropriate scientific field. Shire contends that the person should have a degree in pharmacy or chemical engineering, or an equivalent level of education or training, and at least three years of experience in the field of drug delivery technology or similar technical field of study. Zydus says the person should have a degree in a field related to the pharmaceutical sciences and three to five years of practical experience in formulating drugs.

means "homogeneously distributed," (D.I. 344 at 11). I conclude that the proper construction is the one proposed by Shire.[9]

My construction is supported by the specification, which correlates dispersion with "mixing." Indeed, as Shire points out, the specification uses the term "mixture" or a variation of that terms over twenty times. (*See, e.g.*, *id.* at 2:51-53, 57-59, 3:14-17, 31-39, 40-45, 4:17-18, 5:10-14, 19-20.) Morever, the specification often qualifies the term "dispersion" with the term "homogenous." For instance, the specification describes the lipophilic matrix after granulation as retaining the "homogenous dispersion and matrix structure of the starting mixture," (*id.* at 3:14-17), and most of the Examples refer to homogenous dispersion, (*id.* at 4:10-14, 4:34-38, 4:55-57, 5:31-37). Defining "dispersed" to mean a "homogenous distribution," as Zydus proposed, would thus result in redundant terminology. Finally, the fact that the patent sometimes refers to "simple dispersion" and other times to "homogeneous dispersion" demonstrates that a homogeneous dispersion is one, but only one, type of dispersion. (*Compare, e.g.*, *id.* at 2:50-53 *with id.* at 3:14-17.) Accordingly, the term "dispersed" is construed to mean "sufficiently mixed to incorporate one substance into another."

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[9] My construction is consistent with those of the district courts in the *Osmotica* and *Watson* cases. *See Osmotica*, Doc. 173 at 18; *Watson*, 2013 WL 174843, at *6. The *Mylan* court rejected Shire's proposed construction – the same construction it advances here – and determined that the term "dispersed" should be given its plain and ordinary meaning. *Mylan*, 2015 WL 1345322, at *6. But the court noted that, unlike the defendants in *Watson*, *Osmotica*, or this case, Mylan did not propose a construction that would "erroneously redefine 'dispersion' as only homogeneous distribution." *Id.* at *7. Moreover, the *Mylan* court concluded that there was "no appreciable difference" between the plain and ordinary meaning of "dispersed" and Shire's proposed construction. *Id.* Thus, my construction is not in conflict with that of the *Mylan* court.

E. "wherein the active ingredient is dispersed both in the lipophilic matrix and in the hydrophilic matrix"

Shire contends that the disputed term means "wherein mesalamine is sufficiently mixed to incorporate it within the lipophilic matrix and the hydrophilic matrix." (D.I. 337 at 16.) Zydus argues that the term means "wherein mesalamine is separately added into and homogenously distributed in both the inner lipophilic matrix and the outer hydrophilic matrix." (D.I. 344 at 13.) I conclude that the proper construction of the disputed term is "wherein mesalamine is sufficiently mixed to incorporate it within both the lipophilic matrix and the hydrophilic matrix."[10]

I have already construed "dispersed" to mean "sufficiently mixed to incorporate one substance into another." The remaining question, then, is whether the claim requires the active ingredient to be "separately added" into "both" the inner lipophilic matrix and the outer lipophilic matrix. During the prosecution of the '720 patent, the applicants amended their claims to surrender all embodiments in which the active ingredient was contained completely in the lipophilic matrix. As amended, the patent covers only compositions in which the active ingredient was dispersed in both matrices. (*See* '720 Pros. Hist. at PLMESA03534320-23.) As Shire notes, however, there is nothing in the patent that suggests that the active ingredient must be "separately added" into each matrix. To add that requirement would impermissibly import a process limitation into the composition claim. *See Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1344 (Fed. Cir. 2008) ("Courts must generally take care to avoid reading process limitations into an apparatus claim because the process by which a product is made is irrelevant

[10] My construction is consistent with those of the district courts in the *Osmotica* and *Watson* cases. *See Osmotica*, Doc. 173 at 18-19; *Watson*, 2013 WL 174843, at *6.

to the question of whether that product infringes a pure apparatus claim." (internal citation omitted)). The proper construction should, however, include the modifier "both," to make clear that the active ingredient must be present in both the inner and outer matrices. Thus, I construe "wherein the active ingredient is dispersed both in the lipophilic matrix and in the hydrophilic matrix" to mean "wherein mesalamine is sufficiently mixed to incorporate it within both the lipophilic matrix and the hydrophilic matrix."

F. "consisting of," "consists of," or "selected from the group consisting of"

Zydus asserts that "consisting of," "consists of," and "selected from the group consisting of" are terms of art in patent law that are intended to "signify[] restriction and exclusion." (D.I. 344 at 17 (quoting *Vehicular Tech. Corp. v. Titan Wheel Int'l Inc.*, 212 F.3d 1377, 1382 (Fed. Cir. 2000)).) Zydus argues that, as a result, those terms do not need construction. Alternatively, Zydus contends that the terms should be construed as "exclusionary terms that allow for the inclusion of only the listed substances and excludes all others." (*Id.*) Shire agrees that those transitional phrases signify restriction and exclusion, but it argues that they "do[] not exclude substances unrelated to, or outside of the context of [a listed] element." (D.I. 337 at 18.) Thus, Shire seeks a construction that the terms are "exclusionary terms specifying that an element contains only what is expressly set forth in a recited list, but does not exclude substances unrelated to, or outside of the context of the element." (*Id.*) The Federal Circuit has clearly explained the meaning of such transitional phrases:

> Transitional phrases, such as "comprising," "consisting of," and "consistently essentially of," are terms of art in patent law that define the scope of the claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The phrase "consisting of" signifies restriction and exclusion of unrecited steps or components. Although "consisting of" is a term of restriction,

> the restriction is not absolute. The Patent Board of Appeals has interpreted "consisting of" to "close[] the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith."

Conoco, Inc. v. Energy & Envtl. Int'l., L.C., 460 F.3d 1349, 1360 (Fed. Cir. 2006) (internal citations omitted); *see also Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004) ("'Consisting of' is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim. However, while 'consisting of' limits the claimed invention, it does not limit aspects unrelated to the invention." (internal citation omitted)).

Shire's proposed construction is thus more accurate because it reflects the Federal Circuit's mandate that the transitional phrases do not signify absolute restriction. Nevertheless, I disagree with the inclusion of the phrase "or outside of the context of." That phrase does not appear in any Federal Circuit opinion discussing these terms. Moreover, inclusion of the phrase would, as Zydus notes, create unnecessary ambiguity. Similarly, I agree with Zydus that the case law exceptions to the terms' absolute exclusion are narrow – the Federal Circuit has only mentioned impurities or aspects truly unrelated to the invention. Adding the phrase "outside of the context of" would thus potentially broaden the scope of the exceptions. Accordingly, I construe the phrases "consisting of," "consists of," and "selected from the group consisting of" as follows: "exclusionary terms specifying that the element contains only what is expressly set forth in a recited list, but not excluding impurities and substances unrelated to said element."[11]

[11] My construction is consistent with that in *Mylan* and varies slightly from that in *Watson*, where the district court adopted the construction proposed by Shire here. *Mylan*, 2015 WL 1345322, at *9; *Watson*, 2013 WL 174843, at *8. But, as the *Mylan* court noted, *Mylan*, 2015 WL 1345322, at *9, the inclusion of the specific phrase "or outside of the context of" was not in dispute in the *Watson* case, *Watson*, 2013 WL 174843, at *8, and thus my construction is not in substantial tension with the district court's ruling in that case.

G. "optionally other excipients"

Shire contends that "optionally other excipients" means "excipients, not including coatings, other than those substances forming the inner lipophilic matrix and those compounds forming the outer hydrophilic matrix." (D.I. 337 at 19.) Zydus argues that the term means "excipients that are not part of the inner lipophilic matrix or the outer hydrophilic matrix." (D.I. 344 at 18.) I conclude that the proper construction of the disputed term is "excipients, not including coatings, other than those substances forming the inner lipophilic matrix and those substances[12] forming the outer hydrophilic matrix."[13]

My construction is supported by the specification and the claims themselves. The structure of claim 1 indicates that "optionally other excipients" refers only to excipients that become part of the "oral pharmaceutical compositions," and not to excipients that may be used for coatings. (*See* '720 patent at claim 1.) Claim 1 requires that the oral pharmaceutical compositions contain the active ingredient, mesalamine, and (a) an inner lipophilic matrix consisting of particular excipients; (b) an outer hydrophilic matrix consisting of particular excipients; and (c) optionally other excipients. (*Id.*) Thus, "optionally other excipients" refers to excipients in the oral pharmaceutical composition other than those listed as being contained in the inner and outer matrices. Nowhere in the claim is there a mention of coatings of any kind.

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[12] Shire uses the word "compounds" to refer to the components of the outer hydrophilic matrix, but uses the word "substances" to refer to the components of the inner lipophilic matrix. Because neither party has suggested that the terms have substantively different meanings, for consistency, I refer to the components of both the inner and outer matrices as "substances."

[13] My construction is identical to those of the district courts in the *Mylan* and *Osmotica* cases. *See Mylan*, 2015 WL 1345322, at *7-8; *Osmotica*, Doc. 173 at 19.

Furthermore, claim 3 recites "[c]ompositions as claimed in claim 1, in the form of tablets, capsules, or min[i]tablets," (*id.* at claim 3), and the specification states that "[t]he tablets, capsules, and/or minitablets obtainable according to the invention can optionally be subjected to known coating processes," (*id.* at 3:46-48). Read together, those disclosures support the position that the coating process is not part of the inventive composition in the '720 patent. In addition, none of the Examples in the specification include coatings in the unitary weight of the inventive compositions, ('720 patent at 4:10-6:15), suggesting that the claimed excipients are those found within the oral pharmaceutical composition, not in an optional coating applied after the composition is formed. Accordingly, "optionally other excipients" is construed to mean "excipients, not including coatings, other than those substances forming the inner lipophilic matrix and those substances forming the outer hydrophilic matrix."

V. CONCLUSION

For the foregoing reasons, I will construe the disputed terms in the patents-in-suit consistent with this Memorandum Opinion. An appropriate Order will follow.